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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/314,889	05/19/99	YU	G 1488.0310006

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EXAMINER

ULM, J

ART UNIT	PAPER NUMBER
1646	9

**DATE MAILED:** 09/05/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.  
09/314,889

Applicant(s)

Yu et al.

Examiner

John Ulm

Group Art Unit

1646

 Responsive to communication(s) filed on Jun 16, 2000 This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

 Claim(s) 22 and 27-119 is/are pending in the application.

Of the above, claim(s) 22 is/are withdrawn from consideration.

 Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) 27-119 is/are rejected. Claim(s) \_\_\_\_\_ is/are objected to. Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

 See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

 Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). 3 Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1) Claims 22 and 27 to 119 are pending in the instant application. Claims 1 to 21 and 23 to 26 have been canceled and claims 27 to 119 have been added as requested by Applicant in Paper Number 8, filed 16 June of 2000.

2) Claim 22 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8. The traversal is on the ground(s) that a search of the different inventions in a single application would pose no undue burden. This is not found persuasive because M.P.E.P. 803 states that:

“ For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant.”

Serious burden was shown in the original requirement by the separate classification and separate status in the art of the different inventions. Applicant has provided neither a showing or evidence to the contrary. The fact that searches of the two claimed inventions might overlap is irrelevant since those searches would not be coextensive. Numerous proteins had been isolated before the development of recombinant DNA and numerous DNAs have been isolated without any knowledge of the proteins potentially encoded thereby.

The requirement is still deemed proper and is therefore made FINAL.

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3) Claims 57, 62 to 70, 73 to 81 and 94 to 100 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

“Since the decisions in *In re Weber* \*\*, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.”

The amino acid sequences recited in the Markush groups of claims 57, 70 and 81 lack a common utility which is based upon a common structural feature disclosed as a basis for that common utility. Applicant is required to cancel the claims, or amend the claims to place them in proper form.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4) Claims 27 to 119 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance. This protein is clearly functions as a receptor, however, the instant specification fails to identify any native ligand for this receptor. The specification discloses that the putative

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receptor protein described therein appears to be expressed specifically in lymphocytes and "plays a role in lymphocyte homeostasis". It further discloses that the over expression of this putative receptor in a cell mimics ligand activation of this receptor and that this receptor activation induces cell death. Presumably, an isolated nucleic acid of the instant invention can be employed to produce the putative receptor protein encoded thereby and that this protein can be used to identify ligands thereto which would induce cell death when administered to lymphocytes. The instant specification does not explain the practical advantage of selectively killing lymphocytes nor does it identify that substantial specific benefit which is provided to the public by the disclosure of an isolated nucleic acid encoding a protein which might be used to identify an as yet unidentified compound which can possibly be used to selectively kill lymphocytes..

It is clear from the instant specification that the receptor protein described therein is what is termed an "orphan receptor" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are

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"useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to an isolated nucleic acid encoding a protein of as yet undetermined function or biological significance beyond the fact that it belongs to the TNF receptor family.

Until some actual and specific significance can be attributed to the protein identified in the specification as DR3, or the gene encoding it, the instant invention is incomplete. The protein encoded by a DNA of the instant invention is a compound known to be structurally analogous to proteins which are known in the art as members of the Tumor Necrosis Factor (TNF) receptor family. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which inhibit or induce its activity is clearly to use it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for DR3 then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) Claims 27 to 119 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

6) Claims 43 to 56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims expressly require the biological material recited therein to make the claimed invention. Applicant, their assignee or their agent needs to provide a declaration containing the following:

The identification of the declarant.

A statement that a deposit has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

A statement that the deposited material has been accorded a specific, recited, accession number.

A statement that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. § 122.

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A statement that the deposited material will be maintained with all of the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty years after the date of deposit or for the enforceable life of the patent, whichever period is longer.

A statement by declarant that all statement made therein of declarant's knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternately, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) **and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.** Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession number) number, name and address of the depository, and the complete taxonomic description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7) Claims 42, 56, 69, 80, 101, 110 and 119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite because the identity of the polypeptide being produced by the claimed method is unclear. The act of

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culturing a host cell inherently results in the production of thousands of different polypeptides. It is unclear as to which of these polypeptides the claims are referring.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. 120 states that:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

8) Claims 27 to 119 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Kitson et al. publication (NATURE 384:372-375, 28 Nov. 1996). Because of the rejection of these claims for lack of utility under the first paragraph of 35 USC 112 above, the instant application does not receive benefit under 35 USC 120 from any prior applications.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kuntz can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
JOHN ULM  
PRIMARY EXAMINER  
JAN 2000